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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,415	07/19/2000	LESA J. BEAMER	11034US02/0	2291

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EXAMINER

MARSCHER, ARDIN H

ART UNIT

PAPER NUMBER

1631

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22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/446,415

Applicant(s)

Beamer et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 27, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) 7-14, 24, and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Applicants' arguments, filed 3/27/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The elected, claimed, invention is directed to computer modeling of BPI or related proteins, whereas, in contrast, the present title includes protein compositions, X-ray diffraction, and rational drug design.

NON-STATUTORY SUBJECT MATTER UNDER 35 U.S.C. § 101

Claims 1-6 and 15-23 are rejected under 35 U.S.C. § 101 because the claims are directed to non-statutory subject matter. Utilizing the general guidance for computer related inventions as summarized in the MPEP at section 2106 the first inquiry is directed to what applicants have invented or seek to patent. In the instant application the three-dimensional structure (non-functional descriptive material) of BPI for modeling purposes appears to be the basis for the invention. Then in the MPEP at section 2106, part II, subpart A, the inquiry is directed to what the invention as a whole accomplishes and notes that a useful,

concrete, and tangible result is required. It is noted that instant claims 1-6 and 15-23 fail to cite any limitation that is either concrete or tangible, albeit potentially useful in drug design. Thus, instant claims 1-6 and 15-23 fail in two of the three criteria for statutory subject matter, wherein the statutory requirement therein requires all three criteria to be met. As guided in the MPEP at section 2106, part II, subpart B, a review of the disclosure and specific embodiments has failed to reveal concrete and tangible results for the instant invention. It is noted that fragments and variants are discussed in the latter portion of the discussion in the specification with speculation as to possible usage results, but without proceeding beyond BPI data manipulation to obtain either a concrete or tangible result. As then guided in the MPEP at section 2106, part II, subpart C, a review of instant claims 1-6 and 15-23 also has failed to reveal any concrete and/or tangible result. Focusing on claim 1, for example, reveals modeling of BPI or fragments etc. which is deemed manipulation of abstract ideas in the form of atomic coordinates of BPI. Such abstract data manipulation also fails to produce any concrete and/or tangible result. In summary the instant invention as claimed in claims 1-6 and 15-23 are directed to non-statutory subject matter.

This rejection is maintained and reiterated from the previous office action, mailed 7/29/02. Applicants argue that

the instant modeling claims are more tangible and concrete than the share price calculation in *State Street*.... In response the calculation of a share price permits immediate action in a financial or business action whereas the instant 3-D modeling "may" only result in a drug design that may or may not be tangible and concrete thus making the fact pattern different between the instant application and that of the cited legal decision.

SCOPE OF ENABLEMENT REJECTION

Claims 1-6 and 16-23 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for practicing three dimensional modeling with the atomic coordinates in Table 4, does not reasonably provide enablement for any other BPI protein, fragment, analog, or variant without three-dimensional coordinates as in Table 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of

experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

It has been recognized that the crystallization of a protein in order to obtain suitable crystals for X-ray crystallography is a trial and error process. See Drenth at page 1, lines 1-20, where this trial and error aspect is discussed regarding a number of unknown factors in the crystallization process such as impurities, crystallization nuclei, etc. With several unknown factors and the acknowledgment that the crystallization process to obtain suitable crystals is the least understood step in X-ray structural analysis of a protein, it is reasonable to conclude that steps in this process lack enablement due to unpredictability until atomic coordinates are produced of reasonably small resolution. Another publication indicating that certain crystals are of limited value due to low resolution is that of Benson et al. on page 644, second column, lines 1-6, of

the section entitled "Structure determination". It is noted that the instant application only contains a single Table 4 listing of such atomic coordinates and that claims that are broader in scope beyond requiring the Table 4 coordinates lack enablement due to the unpredictability of making crystals in order to determine three-dimensional structures for modeling procedures.

This rejection is maintained and reiterated from the previous office action, mailed 7/29/02. Applicants argue that the instant claims are directed to modeling and providing a crystal model and not crystallization. In response the practice of the above noted non-enabled embodiments of the instant claims requires the production of new and not presently specifically described atomic coordinates via a method involving crystallization these other embodiments, such as BPI variants etc. Thus, the non-enablement is directed to a lack of predictable methodology for "making" the invention regarding new atomic coordinates for the above noted embodiments.

PRIOR ART

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-6 and 15-23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Balaji et al. (P/N 5,579,250) in view of the legal decision of In re Gulack [703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983)].

Balaji et al. describes methods of drug design via computer modeling. Columns 11-32 details the use of atomic coordinates of a receptor such as a protein wherein drugs or compounds which interact therewith are designed. One of the options for the obtaining of such coordinates is from X-ray crystallography as noted in column 12, line 66, through column 13, line 9. Polypeptide modeling is specifically discussed in column 24, line 50, through column 25, line 26. In columns 11-32, energy minimization, bond angles, etc. are discussed as parameters in said design methods. These descriptions are the instant methods but only missing the specific atomic coordinates of the instantly claim BPI, or related protein, amino acids.

In re Gulack is a legal decision which indicates that nonfunctional descriptive material in a claim does not distinguish the prior art in terms of patentability. It is noted that this is also discussed in the MPEP at section 2106, part VI. In the instant claims the BPI, or related protein, atomic coordinate information is reasonably interpreted as such nonfunctional descriptive material which does not result in a actual physical action in the claimed methods. The computer modeling of BPI, or related protein, is information but not an action and thus this result of the instant claims does not result in a function but rather is a conceptual result only.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform three-dimensional modeling as in Balaji et al. as in the instant claims wherein only nonfunctional descriptive material is additionally present in the instant claims which do not distinguish the claimed method from Balaji et al. according to In re Gulack.

No claim is allowed.

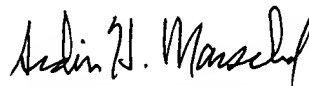
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 27, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER